

III. REMARKS

A. **Claim Status**

Claims 17-40 are re-presented. Some of these claims correspond to claims rejected in the parent application. Some claims contain newly presented limitations. Rennin, which is specifically excluded by some claims, is not disclosed in the specification.

This second preliminary amendment re-presents with underlining the same claims presented in the original preliminary amendment and cross-references the other two related reissue applications, as informally requested by the examiner.

B. **Support for Presented Claims**

The following section shows support for the claims.

17. A process of forming a composition which is storage-stable at 20° C, said composition comprising the steps of:

Claims 1 and 12.
Column 3 lines 1-13.

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellaable and

(b) at least one material to be stored;

(2) evaporating liquid water from said solution to convert said solution into a composition in a glassy state;

wherein said composition has the properties that it is storage-stable and exists in said glassy state when at 20° C;

wherein said composition contains no more than 4 percent by weight of water;

Column 2 line 41.

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution

Claims 1, 2, and 12.
Column 3 lines 1-13.

when at 20° C;

wherein said at least one material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said step of forming comprises heating the combined carrier substance and purified biologically active material to a temperature not exceeding 80° C.

18. The process of claim 17 wherein said step of forming comprises maintaining a sub atmospheric pressure on the combined carrier substance and purified biologically active material while heating the combination to at least 30° C and not exceeding 80° C.

19. The process of claim 17 wherein said carrier substance comprises a water soluble or water swellable synthetic polymer.

20. The process of claim 17 wherein said purified biologically active material is not an enzyme.

21. The process of claim 17 wherein said purified biologically active material is not rennin.

22. The process of claim 17 wherein said purified biologically active material comprises a hormone.

23. The process of claim 17 wherein said purified biologically active

Column 6 lines 22-24.

Column 6 lines 22-24 and 42.

Column 3 lines 65-66.

Claims 1, 2, and 12.
Column 3 lines 1-13.

Claims 1, 2, and 12.
Column 3 lines 1-13.
Rennin is not specifically disclosed.

Support for limitations presented for claim 17.

Support for limitations presented for claim 17.

material comprises immunoglobulin.

24. The process of claim 17 wherein said purified biologically active material comprises a blood clotting factor.

25. The process of claim 17 wherein said purified biologically active material comprises a pharmacologically active protein.

26. A glassy state composition which is storage-stable at 20° C, comprising:

- (1) a carrier substance which is water-soluble or water-swellaable and
- (2) at least one material to be stored which is dissolved in said amorphous carrier substance;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C;

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 2:1 and about 1:1.

27. The composition of claim 26 wherein said composition contains no more than four weight percent water.

Support for limitations presented for claim 17.

Support for limitations presented for claim 17.

Claim 1, and see claim 17 herein.

Column 10 line 9, column 11 lines 8, column 12 line 21, column 13 lines 13.

Column 2 line 41.

28. The composition of claim 26 wherein said ratio is about 2:1.

Column 10 line 9, column 11 lines 8, column 12 line 21, column 13 lines 13.

29 The composition of claim 26 wherein said ratio is about 1:1.

Column 10 line 9, column 11 lines 8, column 12 line 21, column 13 lines 13.

30. The composition of claim 26 wherein said biologically active material is not an enzyme.

See claim 20.

31. The composition of claim 26 wherein said biologically active material is not rennin.

See claim 21.

32. A method of rendering a material storage stable at 20° C which material is unstable in aqueous solution at room temperature of 20° C, comprising the steps of:

Claim 12.

(1) dissolving to form an aqueous solution

(a) said material and

(b) a carrier substance which is water-soluble or water-swellable;

(2) evaporating liquid water from said solution thereby converting said solution into a glassy state composition;

wherein said material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the property that it is storage stable and exists in said glassy state when at 20° C; and

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 1:2 and about 1:1.

33. The method of claim 32 wherein said weight ratio is about 1:1.

34. The method of claim 32 wherein said weight ratio is about 1:2.

35. The method of claim 32 wherein said composition contains no more than 4 weight percent water.

36. The method of claim 32 wherein said biologically active material is not an enzyme.

37. The method of claim 32 wherein said biologically active material is not rennin.

38. A method of forming a composition which is storage-stable at 20° C, said composition comprising:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellable and
(b) at least one material to be stored;

(2) forming said solution containing said carrier substance with said at least one material dissolved therein into a glassy state by evaporation of liquid water to produce said composition;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides,

Column 10 line 9, column 11 lines 8, column 12 line 21, column 13 lines 13.

Column 10 line 9, column 11 lines 8, column 12 line 21, column 13 lines 13.

Column 10 line 9, column 11 lines 8, column 12 line 21, column 13 lines 13.

See claim 17.

See claim 20.

See claim 21.

See previous claims.

nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and wherein said composition contains no more than 4 percent by weight of water; and

wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C; and

wherein said step of dissolving comprises dissolving in an aqueous solution having a pH of about 7.

39. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and is in a glassy state;

(2) at least one material to be stored which is dissolved in said carrier substance; wherein said composition exists in a glassy state at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water;

Examples 5 at column 10 line 17; example 6 at column 11 line 7; example 7 column 11 lines 30-34; example 8 lines 40-41; example 9 column 11 last line; example 10 column 12 line 23; example 11 column 12 line 40-43; example 12 column 12 lines 56-57 and 60; example 13 column 13 lines 5-7.

See previous claims.

and

wherein said biologically active material is not rennin.

40. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellable;

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

wherein said biologically active material is not an enzyme.

41. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution

See previous claims.

at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

wherein said biologically active material is not rennin.

See previous claims.

42. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said biologically active material is not an enzyme; and

wherein said carrier substance does not comprise maltotriose.

See previous claims.

43. A composition which is

Table in column 13.

See previous claims.

storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellable and

(2) at least one material to be stored which is dissolved in said carrier substance; wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said biologically active material is not an enzyme

and is not freeze stable.

44. A method of forming a composition which is storage-stable at 20° C, comprising the steps of:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellable and

(b) at least one material to be stored; forming said solution into a glassy state composition by evaporating liquid water;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution

See previous claims.

Column 1 lines 51.

See previous claims.

at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said biologically active material is not an enzyme; and

wherein said carrier substance does not comprise maltotriose

Table in column 13.



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PATENT TRADEMARK OFFICE

Neifeld IP Law, PC
Crystal Plaza 1
2001 Jefferson Davis Highway
Suite 1001
Arlington, VA 22202

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Date

Respectfully Submitted,

Richard A. Neifeld, Ph.D.
Registration No. 35,299
Attorney of Record

Tel: 703-415-0012
Fax: 703-415-0013
Email: rneifeld@Neifeld.com

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